

II. REMARKS

A. Status of the Claims

Applicants respectfully submit that claims 54-113 are pending. Claims 54, 106-113 have been amended. Claim 58 has been cancelled without prejudice. Claims 1 to 53 and 61 were previously cancelled without prejudice. Applicant respectfully submits that no new matter has been added by virtue of this Amendment. Support for amended claim 54 can be found in from cancelled claim 58 and in the specification.

B. Rejection Under 35 U.S.C. § 102

I. Jancso, et al.

In the Office Action the Examiner rejected claims 54-57 under 35 U.S.C. § 102(b) as being anticipated by Jancso et al.

Applicants respectfully traverse this rejection. To anticipate a claim, an individual reference must teach, expressly or inherently, each and every element in a claim (See: MPEP §2131, referencing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631). The fact that a characteristic may occur or be present in the prior art is not sufficient to establish the inherency of the characteristic. (See: MPEP § 2112, Sec. IV citing *In re; Rijckaert*, 9 F.3d 1531, 1534).

“To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” (Id. citing *In re Robertson*, 169 F.3d 743, 745).

Independent claim 54 has been amended to recite the a synthetic trans-

capsaicin “having a purity of at least about 97%. As conceded by the Examiner in the Office Action at page 3 “the prior art does not teach a capsaicin of about 97% purity.”

Accordingly, the Jancso reference does not expressly or inherently teach a synthetic trans-capsaicin having a purity of at least about 97% as claimed in the present invention. Therefore, amended independent claim 54 of the present invention and the claims that depend there from are not anticipated by the Jancso patent. Applicants, respectfully request that in view of the above arguments, the Examiner’s rejection be removed.

II. Limlomwongse et al as evidenced by Jancso, et al.

In the Office Action the Examiner rejected claims 54-60 and 63-113 under 35 U.S.C. § 102(b) as being anticipated by Limlomwongse, et al. as evidenced by Jancso et al. The Examiner stated that the amount of purity claimed in claims 58-60 “would have been necessarily taught by Limlomwongse et al. because Limlomwongse et al. teaches the capsaicin is synthetically derived and pure therefore it would be approximately 100% trans-capsaicin.”

Applicants respectfully traverse this rejection. The synthetic trans-capsaicin utilized by Limlomwongse et al. would not be approximately 100% trans-capsaicin as asserted by the Examiner. The synthetic trans-capsaicin utilized by Limlomwongse, et al. was manufactured by Sigma Chemical Co. (St. Louis, Missouri). As shown in Appendix A, Sigma-Aldrich provides five (5) capsaicin products, four of which are derived from a natural source (capsicum sp., natural, and puriss.) and not a synthetic source. The Certificate of Authentication of the remaining Sigma-Aldrich capsaicin product (Capsaicin BioChemika, $\geq 97.0\%$ (HPLC) does not specify the source of capsaicin, nor does the Limlomwongse, et al. reference specify the manufacturing steps in preparing the capsaicin, therefore, the Limlomwongse. Et al. reference does not teach “... a synthetic trans-capsaicin having a purity of at least about 97%....” as

claimed in the present invention. Also, because there are five (5) capsaicin products produced by Sigma-Aldrich with varying purities, it is necessarily inherent that synthetic trans-capsaicin utilized had a purity of at least about 97%. Accordingly, the Limlomwongse, et al. reference does not expressly or inherently teach a synthetic trans-capsaicin having a purity of at least about 97% as claimed in the present invention. Therefore, amended independent claim 54 of the present invention and the claims that depend there from are not anticipated by the Jancso patent. Applicants, respectfully request that in view of the above arguments, the Examiner's rejection be removed.

C. Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claim 62 as being unpatentable over Jancso et al. in view of Guenzler-Pukall et al. (U.S. 2004/0204356) and over Limlomwongse, et al. in view of Guenzler-Pukall et al.

As explained above the Jancso, et al. and Limlomwongse, et al. references do not teach or suggest a synthetic trans-capsaicin having a purity of at least about 97% as claimed in the present invention.

The Examiner relies on the Guenzler-Pukall reference for its teaching of suitable carriers for intravenous injection. However, the Guenzler-Pukall reference cannot cure the deficiencies of the Jancso or Limlomwongse references as it does not teach or suggest capsaicin at all, let alone a synthetic trans capsaicin as claimed in the present invention.

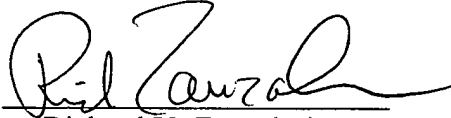
In view of the arguments presented above, amended independent claim 54 and the claims that depend there from are not obvious over the Jancso reference in view of the Guenzler-Pukall reference or the Limlomwongse reference in view of Guenzler-Pukall. Applicants respectfully request that the Examiner's rejection be removed.

III. CONCLUSION

This Amendment is being submitted together with a petition for a one-month extension of time. The Commissioner for Patents is hereby authorized to charge the amount of \$120.00 for the fee due under 37 C.F.R. § 1.17(a)(3) to Deposit Account No. 50-0552. It is believed that no additional fees are due for this submission. If it is determined that any additional fees are due or that any fee has been overpaid, the Commissioner is also authorized to charge said fee or credit any overpayment to Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Richard V. Zanzalari

Reg. No. 49,032

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th floor
New York, NY 10018
(212) 736-1940